

How To Write a Procedure (CFR 493.1251)

A written Procedures Manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

The procedure manual must include the following when applicable to the test procedures:

- Requirements for
 - patient preparation
 - specimen collection
 - labeling
 - storage
 - preservation
 - transportation
 - processing
 - referral
- Criteria for specimen acceptability and rejection
- Microscopic examination, including
 - detection of inadequately prepared slides
- Step-by-step performance of the procedure, including
 - test calculations
 - interpretation of results
- Preparation of
 - Slides
 - Solutions
 - Calibrators
 - Controls
 - Reagents
 - Stains
 - Other materials used in testing
- Calibration and calibration verification procedures
- The reportable range for test results for the test system
- Control procedures, including
 - Type of control (e.g., manufacturer or in-house, electronic)
 - Identity (e.g., normal, abnormal, level I, II, patient or a control)
 - Number and frequency of testing controls
 - Control limits
 - Criteria to determine acceptable control results

- Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability
- Limitations in the test methodology, including interfering substances
- Reference intervals (normal values)
- Imminently life-threatening test results, or panic or alert values
- Pertinent literature references
- The laboratory's system for entering results in the patient record and reporting patient results, including:
 - When appropriate
 - The protocol for reporting imminent life threatening results (panic values)
- Description of the course of action to take if a test system becomes inoperable.